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CONTRACTING ORGANIZATION: Georgetown University

Washington, DC 20007

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	es throughout the United States. The GAO	
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		tions. Enrollment of patients is set to start in
	ies, and the IRB process almost complete in	
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	d deployment evaluation.	
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Introduction:

The Medical Vanguard Diabetes Management Project was designed to deploy an Internet based diabetes management system, MyCareTeam, into a number of existing diverse clinical environments and evaluate how such a stand-alone clinical information system can be integrated into diabetes management program. The diverse environments include the High-Risk Pregnancy Clinic at the National Naval Medical Center (NNMC) and Native American Communities throughout the United States. The GAO Report Executive Guide: Measuring Performance and Demonstrating Results of Information Technology Investments (GAO/AIMD-98-89) will be used as the basis for the evaluation of the technology implementations. Enrollment of patients is set to start in two Native Communities, and the IRB process almost complete in two others. The processes required to implement this technology into diverse communities will be studied. This project has two primary specific aims: clinical deployment and deployment evaluation.

Body:

Statement of Work:

The approved Statement of Work for this project has two primary aims — clinical deployment and deployment evaluation. During this second year, much time has been spent on clinical deployment of MyCareTeam at multiple sites. The administrative processes of setting up subcontracts, working through the Human Subjects Review Processes for each institution, and coordinating with the multiple sites have been challenging. This report will present the challenges and successes of deploying this technology into diverse clinical environments and then identify the next steps once deployment is complete and enrollment and operations can begin.

Clinical Deployment:

As we deploy MyCareTeam in multiple Department of Defense (DOD) and Native American healthcare environments, we approach this technology insertion from a global perspective that includes concerns of the enterprise (DOD or Native American facility), existing diabetes management programs, healthcare units, clinical staff, and patients. The goal of the deployment of MyCareTeam is to improve the effectiveness of various existing diabetes management programs for the medical beneficiaries in the DOD as well as Native American Communities as measured by improved health outcomes and clinical care delivery.

The clinical deployment portion of this project focuses on determining the most efficient and effective way to identify and organize the roles and responsibilities of individuals within the healthcare enterprise and the insertion of MyCareTeam within the healthcare delivery system. A comprehensive systems approach to the integration of MyCareTeam into the different clinical environments has been undertaken.

All clinical deployments go through many stages before MyCareTeam can be used effectively. Program setup and recruitment are two critical components of deploying MyCareTeam into an existing clinical environment. The stages of (A) program setup and (B) recruitment and operations that are critical to a successful deployment of MyCareTeam are described here.

(A) Program Setup

1. secure subcontract for each group

At the end of the second year of funding, we still encounter human subjects' protection issues that have affected the creation of new subcontracts. The process for creating new subcontracts has not changed since year 1 and we still request approval from a member of the National Congress of American Indians President's Taskforce on Healthcare Technology to ensure that the monies allocated and distributed to the Native Communities are done so fairly. There are subcontracts in place with the Mandan, Hidatsa & Arikara (MHA) Nation, Poarch Band of Creek Indians (PBCI), and the Native Hawaiian Health organization – Papa Ola Lokahi. The subcontracts with the Nez Perce and the Tlingit & Haida Tribes of Alaska will be executed as soon as final human subjects' protection approvals are received. The Wampanoag, Rosebud Sioux, and Mescalero tribes have not progressed despite our efforts to include them. Therefore, no progress has been made to bring them into the project.

The Native Communities submit quarterly reports to us which outline their progress and include an invoice for project related expenses. Upon recipt of year two funding, the subcontracts for MHA Nation, PBCI, Papa Ola Lokahi and the Cooperative Research and Development Agreement (CRADA) with NNMC were modified to reflect a two-year agreement. They were modified again to grant a no-cost extension when Georgetown received a no-cost extension from the United States Army Medical Research Acquisition Activity. Georgetown University maintains its CRADA with the National Naval Medical Center instead of a subcontract agreement. The CRADA guides the use of personnel, resources, and equipment between the Navy and Georgetown University during the course of this project.

2. create a local project team including clinical and project management personnel
Local project teams are forming or have formed for all engaged communities. These teams
include clinical, administrative, and project management personnel. Some sites have
identified a physician as a member of the team, but most often a nurse or diabetes educator
has primary responsibility for interacting with the patients using MyCareTeam. Within each
community, an advocate within the health clinic, an administrator or a provider with diabetes
knowledge and experience, needs to be identified. This person drives the program from
within the clinic. Their job is to coordinate the clinical personnel that will work on the
project, identify patients for recruitment, deal with contractual and human subjects' issues,
and direct the adjustments that need to be made to the MyCareTeam application. A team of
individuals will be involved from the start – but having an advocate makes coordination
between the clinical and technical teams run smoother.

The PBCI had much staff turnover this year at their health clinic, which negatively affected the start of the study. Two Physicians, the clinic administrator and Principal Investigator, and a nurse all left the health clinic this year. The study nurse remains and has been taking on more responsibilities until the other persons are replaced. The program manager at the MHA Nation has worked closely to bring together a clinical and administrative team there. The project team within the Native Hawaiian Health System (NHHS) has changed often over this past year. It has finally settled down and Principal Investigators from each of the two health clinics involved have been identified, and an administrative person from the NHHS is

coordinating the two clinics and clinical consultants to work with each site. NNMC has a project team consisting of physicians, residents, and nurses. The nurses deal directly with the high risk patient population to recruit and manage their care, but the residents are responsible for communicating with the patients via MyCareTeam.

3. define the existing health services at each site

NNMC is a full service medical institution providing primary and specialty care to all members of the armed services and their families. NNMC has the facilities to perform lab tests, surgery, rehabilitation, and other services associated with a full service in—and outpatient medical institution. The Native communities engaged in the project tend to be more single clinics focusing on primary care with some specialty services provided. Most do not have surgery departments, rehabilitation, or therapy (PT, OT, or radiation). They do provide pharmacy services, some provide laboratory services, and most have a nurse practitioner or family medicine doctor that visits the clinic regularly but is not on full time staff at the clinic. Some patients in the Native Communities need to travel many hours to the nearest hospital or specialty clinic (like dialysis) and thus access to care for these populations is limited and difficult.

4. define the existing diabetes services at each site

NNMC has two clinics that focus on the treatment of pregnant women with diabetes. They have a gestational diabetes mellitus (GDM) clinic that focuses on women who are pregnant and develop diabetes during their pregnancy but can control their blood sugar levels through diet and exercise. Most of these women do not take medication for their GDM. The other clinic is the Complex Obstetrics (COB) clinic that focuses on pregnant women with pre-existing diabetes or pregnant women who developed GDM but need insulin or oral medications to control their diabetes. Patients from both of these clinics will be enrolled in the study as long as they use a glucose meter to track their blood sugar readings.

Most of the Native Communities have implemented diabetes clinics within their primary medicine clinics. Some of the communities have endocrinologists as consultants that visit their patients periodically or to which they refer their patients, all have glucose meters and supplies available to their patients at no cost, and all of the clinics provide educational classes to their patients on diabetes. One of the clinics provides a monthly foot clinic where patients can get appointments to have their feet examined and cared for. (Foot ulcers leading to amputation is a very serious and common complication of diabetes). One of the sites we are currently working with was using a standalone software application to read their patients' glucose meters when the patients came in for their regularly scheduled visits. All are excited about using our technology.

The table below shows the statistics for each clinic enrolled in the project. It identifies baseline information regarding the clinic and existing diabetes programs.

	Number of members	Number of diabetics	Number of clinics	Glucose meter
National Naval Medical Center		15-30 at a time	2 - GDM and COB	AccuChek Advantage
MHA	10800	680	5	AccuChek Advantage
PBCI	2260	300	1	Precision Xtra
Tlingit & Haida	6000	160-180	1	AccuChek Advantage
Nez Perce	5000	406	2	OneTouch Ultra
Hawaiian Natives Na Puuwai	65	18	4	OneTouch Ultra
Ke Ola Mamo	1485	82	1	OneTouch Ultra

5. define the technology resources available

The implementation of MyCareTeam requires some home monitoring technology. Patients connect their glucose meter to a vital signs modem device which connects directly to a phone line. The modem reads the data from the glucose meter and transmits the readings to the MyCareTeam database. Initial concerns about the availability of telephone lines, computers, and Internet access within some of the more remote Native communities has not shown to be a problem. Each participating site has assured us that access to telephone lines will not be a problem and that technical barriers to transmitting their blood glucose readings to the MyCareTeam database will not be an issue.

Access to computers and knowledge of the Internet may be more difficult. Most sites, excluding NNMC, felt that a small percentage of their mostly adult patients with type 2 diabetes would have access to a computer and even smaller amount with Internet knowledge. Therefore, most of the sites have decided to place public access computers with Internet access in key locations that make them accessible to patients. The sites also recognize that it may be necessary to provide individuals that can train patients on using the computer to access MyCareTeam and also to help patients review their data.

High speed access to the Internet from the public use machines should be available for most sites. Most patients with a computer in their home or a family member's home would use dial-up access to the Internet. A toll-free number is in place at the ISIS Center, Georgetown University to receive the glucose readings from the patients modem devices. The modem devices are pre-programmed to send data to this number before they are distributed to patients.

6. define the clinical protocol to be carried out

Each site determines for itself the best way to integrate MyCareTeam into their existing diabetes management program. The protocols for each of the Native communities and the NNMC have been defined and are summarized here. Each site will survey their enrolled patients within 2-4 weeks of enrollment and then again 2-4 months later. A copy of the survey is included in Appendix A.

Mandan, Hidatsa and Arikara Nation: Patients will be recruited from the Parshall and White Shield Health Facilities on the Fort Berthold Reservation. The project investigators will

select participants who are compliant with their treatment regimen but who still have diabetes that is not well controlled. Participants will also be selected on their ability and willingness to access MyCareTeam via the Internet for a period of six months as well as the following criterion: A1C greater than 8 in the last two months; currently using a standard glucose meter; over 18 years of age; access to a standard telephone line; ability to read and write English; and read a computer screen. Once selected, these patients will be followed by an RN from the Parshall or White Shield Health Facilities. Patients will be asked to transfer their glucose meter data weekly to the MyCareTeam secured database. Once the data is available on MyCareTeam patients and providers will review the data and communicate via the site. Changes in medication regimen and suggestions for diet and exercise adjustments can and should be made through MyCareTeam. MyCareTeam will be used as part of routine care by health facility staff in managing the recruited diabetic patients during this evaluation project.

Patients participating in this project will also partake in two telephone surveys at 2-4 weeks after enrollment in the study and the second 2-4 months later. The surveys will help us to understand an individual's reaction to the technology implemented through MyCareTeam, how the patients like communicating with their care providers over the Internet, and their feelings towards the educational materials on the site. Data from the surveys will be analyzed and used to make changes if and where deficiencies are found in the MyCareTeam system. Throughout the study, we will continue to reassess the system after each group of five patients until deficiencies are no longer found.

Poarch Band of Creek Indians: Like the MHA Nation, the PBCI have a similar clinical protocol. Patients will be recruited by the project investigators based on an identical set of inclusion criteria. Study participants will come from a population of diabetic patients seen at the PBCI Health Clinic, the only health facility at the reservation. All providers involved will be employees of the health clinic. The nurses will review the data via MyCareTeam and communicate information back to the patient's physician if necessary or the physician will have permission to access the data on MyCareTeam if desired. Data collected during the telephone surveys will be used to adjust this technology to address both cultural and clinical diversity.

Nez Perce: A part time registered nurse and a full time program assistant will be hired by the Nimiipuu Health Clinic to conduct this study. Once these individuals are trained, they will train the four provider/nurse teams at Nimiipuu Health who work with diabetic patients, the pharmacist, the nutritionist, and the diabetes educator. Those patients who enroll will be monitored by the MyCareTeam nurse and program assistant as well as the provider/nurse team assigned to the patient's care. The same inclusion criteria mentioned above will be used at the Nimiipuu Health Clinic.

Again, the same telephone surveys will be processed to understand an individual's reaction to the technology implemented through MyCareTeam, how the patients like communicating with their care providers over the Internet, and their feelings towards the educational materials on the site. This information will be examined each group of eight responses are

received in order to make changes if and where deficiencies are found in the MyCareTeam system. The system will be assessed until deficiencies are no longer found.

Tlingit & Haida: For this segment of the study, patients will be recruited from the SEARHC Medical Center in Juneau, Alaska. As at other research locations, the project investigators will select those patients who have poorly controlled diabetes but who are able and willing to access MyCareTeam via the Internet for a period of six months. The inclusion criteria will also be the same as mentioned above. During the course of the study, these patients will be followed by the research team at SEARHC JMC using the MyCareTeam system as part of routine care by the staff.

Data collection and the use of a telephone survey administered at the beginning and again halfway through the study will also be utilized at this location.

National Naval Medical Center: Patients are being recruited from the Complicated Obstetrics (COB) and the Gestational Diabetes Mellitus (GDM) Clinics at NNMC in Bethesda Maryland. Subjects for the study come from a population of pregnant women who have either preexisting diabetes or who have been diagnosed with gestational diabetes. Patients are eligible for the study if they meet the following criteria: pregnancy is complicated by either type 1 or 2 diabetes or patient is diagnosed with gestational diabetes; are less than 32 weeks pregnant they regularly test blood glucose levels using a standard glucose meter; they have access to a standard telephone line; can read and write English; and are over 18 years of age.

Patients transfer their blood glucose readings twice a week to the MyCareTeam secured database using the AccuLink Modem. The GDM and COB residents and nurses examine the information online. The resident can change orders for the patient's regimen and message the change back to the patient via MyCareTeam. Patients are instructed to review their own data on MyCareTeam and to look for and send messages to their providers using the system. Patients are given a survey two-four weeks after enrollment and again at approximately 35-38 weeks of pregnancy. The survey helps us to understand their reaction to the technology implemented through MyCareTeam, how they felt about communicating with their care provider over the Internet, and their feelings towards the educational materials.

7. determine where the database and web servers will be hosted and managed
Due to monetary constraints and technical expertise, all sites have opted to have the ISIS
Center at Georgetown University host the web and database servers. Toll-free telephone
numbers have been setup to facilitate the transfer of data directly from the glucose meters via
the modem devices to the MyCareTeam database. The computer facility at the ISIS Center is
a locked room in a secured facility. It is protected by electronic firewalls and VPNs as need
to ensure the safety and integrity of the clinical data.

8. secure human subjects approval from all necessary institutions
Human subjects' protections are a large piece of getting this program underway. Before
recruitment of study participants can begin, authorization must be received from three
separate human subjects approval agencies or institutional review boards (IRB). The first

agency is Georgetown University. We first received expedited review approval from the Georgetown University IRB on August 21, 2003. We have since received two additional continuing approvals with the next due on June 13, 2006.

The second human subjects' approval comes from the regional IRB for each of the American Indian, Alaskan Native and Native Hawaiian communities and NNMC and is referred to as the primary IRB approval. Each study site submits a protocol and consent form adapted to their individual needs. The Native American and Alaskan Native communities will receive approval from the Indian Health Service (IHS) IRB committees. For those IHS sites where there is currently no active IRB, authorization will come through IHS Headquarters in Bethesda, Maryland. These IHS area IRB committees are located in: Anchorage, Alaska; Aberdeen, North Dakota; and Portland, Oregon; Primary approval for the Native Hawaiian study will come from Papa Ola Lokahi, a Native Hawaiian Healthcare System providing human subjects approval on projects related to Native Hawaiian Healthcare. NNMC has its own IRB committee. The third and final authorization comes from the Human Subjects Research Review Board (HSRRB)/Office of Regulatory Compliance and Quality (RCQ), United States Army Medical Research and Materiel Command. This is referred to as secondary approval.

The chart below shows the dates that primary and secondary IRB approval was received for each site. Secondary approval is still outstanding for the Tlingit & Haida Tribes of Alaska and the Nez Perce of Idaho. The Native Hawaiian sites have revised their protocol a number of times based on feedback from IRB members, but have not submitted the protocol and consent forms as of August 31, 2005.

Approval Information

Institution	Primary Approval	HSRRB Approval	Continuing Review Approval Due			
NNMC	1-25-05	1-4-05	6-1-06			
MHA	5-5-05	6-15-05	11-20-05			
PBCI	9-1-04	3-17-05	8-31-06			
Tlingit & Haida	8-31-05	pending	8-31-06			
Nez Perce	6-6-05	pending	6-6-06			
Hawaiian Natives Na Puuwai Ke Ola Mamo	pending	pending	n/a			

9. review the MyCareTeam site for modifications, setting defaults, creating accounts During this past year, demonstrations of the MyCareTeam application were made to the Nez Perce Tribe, Tlingit & Haida Tribes, and the Hawaiian Native Communities with the goal of identifying those areas of the site that require modification. During the first year of the project, the IHS diabetes curriculum was integrated into the web site to provide diabetes education materials to the Native communities. The PBCI, MHA Nation, Nez Perce, and

The Hawaiian Native communities identified areas of the application that should be modified to make the software more culturally appropriate. The changes have not been implemented but will be done once IRB approval is closer to being approved. The Hawaiian Native communities will also provide their own educational materials that will be incorporated into the site for that population. The look and feel of the lobby has been updated to include a more Native looking receptionist and to use earth tones in the walls, carpets, and lobby furniture.

Appendix B contains screen shots of the MyCareTeam application that show changes made for specific sites. A new reception area was created to be more appropriate for Native Communities. Many changes were implemented for NNMC since treating pregnant women with diabetes is more intense than treating non-pregnant type 1 or type 2 diabetic patients. The changes in the blood glucose log book, and a sample of the categorization process that all patients at NNMC must go through is presented in Appendix B.

Configuration of the sites for the MHA Nation, PBCI, and NNMC were completed. The building of the sites for the Nez Perce, Tlingit & Haida Tribes, and the Hawaiian Native communities will occur in the third year of the project, prior to or at the same time the clinicians are trained to use MyCareTeam.

10. procure technology including blood glucose meters, modem technologies, cables, computers, install communications lines, setup telephone numbers

The technology necessary to transfer blood glucose readings from the glucose meters to the MyCareTeam database has been procured for the NNMC, MHA Nation, and PBCI. NNMC and MHA Nation use the AccuChek Advantage glucose meters and thus the AccuLink modem to transfer the data from the meter to the database. Through and agreement with Roche, the modems are purchased by each site for about \$60 plus \$30 for a cable. We negotiated that discount price of the modem as well as receipt of four free cables for each 20 ordered. Towards the end of the second year, Roche informed us that they are discontinuing the manufacture of their AccuLink modems. They agreed to keep enough meters on hand to allow us to complete our study based on our enrollment numbers. They have also discounted the meters a bit further so that the cost to each site will be reduced.

PBCI uses the Precision Xtra meter and thus uses the AeroTel TeleCliniQ to transfer the blood glucose readings from the meter to the MyCareTeam database. A negotiated price of \$150 per modem was arranged with AeroTel and the users buy the cables directly from the meter manufacturer. The manufacturer has provided some cables free to the site.

NNMC, MHA Nation, and PBCI have each ordered an initial 20 modern devices and cables to get their projects started.

A second toll-free telephone number was installed at the ISIS Center to accept the data transmitted from the TeleCliniQ devices from all of the sites, regardless of location. Internet access will not be available through this toll-free phone number. The toll-free number for the

AccuLink modem was setup during the first year of the project. It also restricts Internet access through that phone number.

11. train clinical personnel

Retraining has occurred for the key clinical staff at the MHA Nation, PBCI, and NNMC. This training was done as a "train the trainer" session. These trainers then will train the other clinicians at their site. Because of location and our existing CRADA with NNMC, we provide a certified diabetes educator to the NNMC to aid in training their clinicians and handling administrative issues such as enrolling patients, training the users on the system, entering lab results and entering medications. She also trains and works with the clinicians using the system, as needed

(B) Recruitment and Operations

1. Define inclusion and exclusion criteria for patient participation

Native American Sites:

Inclusion	Exclusion
Have type 1 or type 2 diabetes mellitus that	Less than 18 years of age
has been diagnosed for at least 6 months.	
Have an A1c value ≥ 7 in the last two months	Unable to read and write English
Currently using a standard glucose meter	Unable to read a computer screen
Have access to a Plain Old Telephone	
System (POTS) line	

National Naval Medical Center:

Inclusion	Exclusion
Pregnancy is complicated by either type 1 or 2 diabetes or patient is diagnosed with gestational diabetes	Less than 18 years of age
Patient regularly tests blood glucose levels using a standard glucose meter	Patient has a significant medical co- morbidity that would inhibit their ability to use MCT
Have access to a Plain Old Telephone System (POTS) line	Patient has a history of serious psychiatric disorder
Patient can read and write English	Patient's physician has objections to her participating in the study
Have access to a computer and the Internet	

2. identify recruitment procedures

Each site will determine the best way to recruit their patients. Since we are working directly with personnel at the different clinics, the clinic personnel will be familiar with the patients and will be able to talk with them directly about participation. Whether to use public announcements, brochures, or flyers for recruitment will be decided by each site individually.

Site	Recruitment Procedure
National Naval Medical Center	Study nurse meet with obstetrical clinic staff

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Bethesda, Maryland	weekly to identify those patients who meet inclusion criteria. The study nurse then schedules a time to meet with these patients, reviews all study procedures and invites the patient to participate. If the patient consents
	to enroll in the study, enrollment procedures are followed according to NNMC IRB protocol and patient training is completed.
Poarch Band of Creek Indians	Individuals will be recruited from a
Atmore, Alabama	population of patients receiving diabetes care from the tribal health clinics. The project
MHA Nation	investigators will select participants who are
New Town, North Dakota	compliant with their treatment regimen but who still have diabetes that is not well
Nez Perce Tribe	controlled. During the period of study, a
Lapwai, Idaho	diabetes nurse or member of the research team will speak to patients who meet the
Tlingit & Haida Tribes Juneau, Alaska	inclusion criteria. All individuals who will be involved in the consenting process have completed the NCI Human Subjects Training Program. After informing the patient that they are eligible to participate, the nurse or team member will give the patient a brief description of the project, and, if the patient indicates an interest in participating, that person will then review the consent form answering any and all questions the patient may have. If the patient consents to enroll in the study, enrollment procedures are followed according to local IHS area IRB
	protocol and patient training is completed. The original signed copy of the consent form will be placed in the patient's medical record and the patient will also receive a copy for their records.

3. identify incentives, if any, that will be used

Patients participating from the Parshall and White Shield Health Facilities of the MHA Nation will receive a small gift such as a t-shirt or a coffee mug for being in this study. Those patients recruited from the Nimiipuu Health Clinic from the Nez Perce reservation will be given a small gift at the time they enroll in the program. If they continue to participate in the study they will receive other gifts after two, four and six months.

4. gain consent

Consent forms have been created and final approval received for the NNMC, MHA Nation, and PBCI. The consent forms for the Nez Perce and Tlingit & Haida tribes are under review with the appropriate IHS human subjects committees. The consent form for the Hawaiian Native communities is still under development.

5. Summary of Program Setup

A summary of the progress of the program setup is provided below in Table 1.0.

Principal Investigator: Seong K. Mun, PhD

	$\overline{}$			_		_	_					_					
NNMC		X	X	×	×	×	×	×	×	×	×	×		X	×	None	6-X
Mescalero																	
Rosebud																	
Nez Perce		Ongoing	×	×	×		×	×	Ongoing								
Gay Head				×	×			X									
Tlingit and Haida		Ongoing	X	×	×		×	×	Ongoing							None	
Papa		×	×	×	×	×	×	×	Ongoing	Ongoing		X - retrain					
PBCI		×	×	×	×	×	×	×	×	×	×	×		×	×	None	
MHA		×	×	×	×	×	×	×	×	×	X	X		×	×		
	(A) Program Setup	Subcontract/CRA DA	Project Team	Health Services	Diabetes Services	Technology Resources	Clinical Protocol	Host Servers	Human Subjects	Modify MyCareTeam	Procure Technology	Training	(B) Recruitment	Criteria	Procedures	Incentives	Gain Consent

Table 1.0 Program Setup

X - completed

Deployment evaluation

Introduction

This section focuses on evaluating whether the insertion of MyCareTeam into routine delivery of healthcare services and specifically chronic disease management was effective.

The earlier indications of the effectiveness of MyCareTeam as a stand-alone specialty disease management e-health system are encouraging. However, insertion of MyCareTeam into multiple diverse clinical environments presents new technical, clinical, management, and cultural challenges.

Recruitment has begun at the NNMC; however, we have not enrolled enough subjects or collected enough data to begin our analysis in full. Therefore, in this section we will begin to present some baseline statistics wherever possible.

Evaluation Measures

To measure the success of the clinical deployment of MyCareTeam in the different clinical environments (DOD facility and Native American communities) we look at individual measures related to recruitment, clinical monitoring, treatment, and clinical outcomes. Different items of measurement have been identified for each of these areas and we will gather the data for each of these measurements directly from the clinical database.

Evaluating Recruitment

To determine if the recruitment procedures were successful, the following information will be collected throughout the recruitment period:

- number of possible participants
- number of patients approached about participating
- number of patients agreeing to participate

Twenty-five pregnant women with diabetes were seen at the NNMC Complicated OB and Gestational Diabetes Clinics from January 25 through August 31, 2005. All of the women that met the IRB criteria were approached to participate. Nine agreed to participate and 16 were found ineligible due to their advanced stage of pregnancy, use of an insulin pump instead of insulin injections, or refusal to participate in the study. Recruitment will continue into year three in an effort to enroll 40 patients before the end of the study.

Evaluating Compliance with Clinical Monitoring

- frequency of blood sugar testing
- frequency of sending in BG values
- frequency of reviewing BG data and other clinical info by patient
- frequency of reviewing BG data and other clinical info by provider
- frequency of sending comments or messages

The women of the NNMC are asked to check their blood sugar readings between 4 and 9 times per day depending on the patient. Data will be analyzed for the patients by looking at the frequency with which they test their sugars compared to what they were asked to do. These

values are stored in or can be calculated from the MyCareTeam database. Similarly, the frequency with which patients and providers review data in the database and message one another can be determined from the data stored in the MyCareTeam database. Since only 9 patients are currently enrolled in the study at NNMC, we have not begun analyzing the data received so far.

Treatment Changes

- number of changes in medications by care provider
- Suggested diet or exercise changes by care provider
- Number of messages sent to patient with clinical content, suggestions, or advise

The amount that patients and providers message each other, the types of messages they send and the frequency with which providers make adjustments in medications online provide an indication of how accepted the technology is and how useful each side thinks it is. This coupled with results from the patient satisfaction surveys will be used to determine the success of the technology insertion. Again, data analysis has not begun.

Assessment of Clinical Outcomes

- Change in A1c
- Change in Cholesterol measures
- Change in BMI
- Change in numbers of hypo- and hyperglycemic events
- Weight of baby at birth (for NNMC)

Diabetes outcomes are measured by the above clinical parameters. Previous studies of MyCareTeam have shown improvements in A1C, cholesterol and BP while showing a decline in BMI (Smith, Levine, et al, 2004; McMahon, Gomes, et al. 2005). It is expected that this study will show similar results. Patients will have regular lab tests and those values will be entered in the MyCareTeam secured database. We can then use the data from the MyCareTeam database to analyze the clinical outcomes of the patients enrolled. As stated above, we will look at the groups of individuals that showed the largest improvement in clinical parameters and determine the characteristics of the population as well as the actions of those patients to determine the most effective use of MyCareTeam.

Other process parameters that we will track and analyze include those associated with inserting, maintaining and supporting the technology. These include the Use of the MyCareTeam technologies, training users on the system, and the support that was required and provided.

Use of Technology

- Frequency of use
- Ease of use
- Most used features

The frequency of use of MyCareTeam by patients will be collected as stated earlier - by reviewing the audit trails maintained within the MyCareTeam application. These audit trails track when users log into and out of the system and thus how long they are engaged can be

calculated. We track how often the patients engage in some of the features of MyCareTeam like exercise tracking, communicating with their providers, and maintaining their "other medications" list. These values plus a short survey on their perceptions regarding ease of use, features they like, and those they say they use most will be used to evaluate the acceptance of the technology by the patients. We have begun collecting this data on the NNMC patients who have been enrolled in the study. Data collection for NNMC will continue, and will begin for the Native Communities throughout the third year of the study.

We also track how frequently providers use the system – however, they may be more likely to use the system even if they don't find it intuitive or easy to use if their patients use it. We have started collecting data on the providers at the NNMC and will continue to do so throughout the third year. Data collection of providers use at the Native Communities will begin as soon as patients are enrolled.

Training

- How long did initial training take
- · How many technical questions were raised

We will keep complete records during the training sessions to determine how long it takes to train the providers and the types of questions they have during the training. It is our goal to streamline the training sessions so that it does not take the providers more than 1-2 hours to be trained and feel comfortable to use the system and to train their patients in its use. We have had training sessions for NNMC, MHA Nation, and PBCI providers. The MHA Nation and PBCI providers were trained twice. The first time was in year one, over one year before human subjects' protection was received and therefore retraining was necessary. They were both retrained recently and patient enrollment should begin early in this third year.

Each site is asked to send 1 or 2 providers to our facility for training. At this time, we train them on all aspects of MyCareTeam. They are trained as providers to care for their patients, as trainers to show patients how to use the system and train other providers back at their facility, and as administrators to enroll patients and other providers. They are also trained on the use of the modem technology that each site is using for their patients to transmit glucose readings into the MyCareTeam database. The entire training takes about 5-6 hours and the outline of what is covered is provided in Appendix C.

Support

- Number of support calls received
- Number of bugs reported
- Number of fixes made
- Amount of time MyCareTeam was down

Enrollment of patients at NNMC began February 2005 and continued through the end of the second year of the study August 30, 2005. During that time, three support calls were received and logged. One was from a provider that forgot their password, and the other two were because the provider could not see patient data that was in the database. All three of these issues were resolved quickly.

Support logs track the numbers and types of support questions that are raised, how they are fixed, and the length of time between the support request being filed and the resolution of the problem. E-mail, telephone, and messages from within MyCareTeam are all available for providers to register technical problems or questions.

Chain of Events Analysis

No Chain of Events Analysis has begun.

Key Research Accomplishments:

Mandan, Hidatsa, and Arikara Nation (MHA):

- Sub-contract is in place contract extension is pending;
- 2. Key personnel at the MHA clinics are in place and awaiting start of the project. Bruce Hall, the project manager, oversees the project;
- 3. Aberdeen Area Indian Health Service Institutional Review Board approval (primary IRB) has been granted for MHA Nation last year; the Human Subjects Research Review Board (HSRRB)/Office of Regulatory Compliance and Quality (RCQ), United States Army Medical Research and Materiel Command approval has been granted;
- 4. Clinical personnel were re-trained;
- 5. Technology to be used has been acquired Patients use Roche AccuChek Advantage glucose meters and 20 Roche AccuLink modems and cables were acquired to facilitate data transfer; and
- 6. The Indian Health Service Diabetes Curriculum implemented into MyCareTeam last year for diabetes education will be used by their patients.

Poarch Band of Creek Indians (PBCI):

- 1. Sub-contract including the extension is in place;
- 2. Key personnel have been identified Annette Hicks, the clinic administrator left the health clinic towards the end of the year and a new administrator was recently hired. A new PI needs to be identified. In the meantime, Donna Johnson, a certified diabetes nurse, is working closely with us to get the technology setup and begin recruitment;
- 3. MyCareTeam is to be implemented in one health clinic located on the reservation;
- 4. Precision Xtra glucose meters will be used with the AeroTel TeleCliniQ modem to transmit the blood glucose readings directly from the meter to the MyCareTeam database; 20 TeleCliniQ modems have been purchased at a reduced purchase price negotiated with AeroTel.; 20 cables were procured from the Precision representative;
- Clinical personnel were retrained;
- 6. Final IRB approval was received from the IHS and from the DOD human subjects' boards this year.
- 7. The Indian Health Service Diabetes Curriculum implemented into MyCareTeam last year for diabetes education will be used by their patients.

Papa Ola Lokahi

1. Sub-contract including the extension is in place;

- 2. We continue to work closely with Papa Ola Lokahi, the key group overseeing the implementation of the project at two health clinics, to create the human subjects protocol and consent forms. The documents have not been submitted to the Papa Ola Lokahi IRB, but should be submitted early into the third year.
- Ke Ola Mamo on Oahu and Na Pu'uwai on Molokai, the two clinical site to carry out the study, have identified the project staff including clinical personnel and project administrators;
- Comments were received from both clinical sites and Papa Ola Lokahi regarding the
 adjustments to the site that they would like to see. Further discussions are pending IRB
 approval.
- 5. OneTouch Ultra glucose meters will be used with the AeroTel TeleCliniQ modem to transmit the blood glucose readings directly from the meter to the MyCareTeam database; a reduced purchase price has been negotiated with AeroTel.; software developed by Georgetown University is available to read data directly from the OneTouch Ultra meter connected to a PC in case it is required for a community PC; No modems or cables have been ordered as yet.
- 6. Educational materials have not been identified

Tlingit and Haida

- 1. Final approval to participate was received from SEARHC's Board of Directors on behalf of the Tlingit & Haida Tribes.
- Verbal approval by the Alaska Area Indian Health Service IRB was received on Aug 31, 2005. Once written approval is received, the items will be submitted to the DOD Human Subjects' Board.

Nez Perce

- Portland Area Indian Health Service Institutional Review Board approval (primary IRB)
 was granted for the Nimiipuu Health Clinic on June 6, 2005. All documents, except the
 Human Subjects Training records for the clinic, were forwarded to the Human Subjects
 Research Review Board (HSRRB)/Office of Regulatory Compliance and Quality (RCQ),
 United States Army Medical Research and Materiel Command. HSRRB will review the
 documents after they receive the training records from Nimiipuu Health research team.
- 2. Sub-contract and a Data Sharing Agreement have been sent to Nimiipuu Health for review and approval. The data Sharing agreement was at the request of the Portland Area IHS IRB.
- 3. Nimiipuu Health has identified a full time project manager and a half-time nurse to be hired specifically to work on the project. Their start/hire date is pending the sub-contract completion process.
- 4. Clinical personnel are tentatively scheduled to attend training in October.
- 5. Technology to be used-OneTouch Ultra glucose meters and AeroTel TeleCliniQ modems have not been purchased yet. Purchase is pending completion of the sub-contract. A reduced purchase price has been negotiated with AeroTel; software developed by Georgetown University is available to read data directly from the OneTouch Ultra meter connected to a PC in case it is required for a community PC.
- 6. The Indian Health Service Diabetes Curriculum implemented into MyCareTeam last year for diabetes education will be used by their patients.

Wampanoag Tribe of Gay Head

- 1. No further progress has been made with this tribe
- 2. The president of the tribe was not re-elected and interest in the project has waned since then.

Rosebud Sioux

- 1. Contact was made with different tribal members to locate the person most interested in the project.
- 2. No further progress.

Mescalero

1. No further progress. They have chosen not to participate at this time.

Oglala Sioux

- 1. The Oglala Sioux showed early interest in participating in the project as a replacement for the Mescalero.
- 2. Initial contact was made, and the discussions are ongoing with the head of the Indian Health Service clinic on the reservation.
- 3. A survey was given to the IHS clinic director regarding services offered at the clinic, specifically related to diabetes as well as information on the numbers of diabetic patients seen at the clinics. The survey has not been returned.

National Naval Medical Center

- 1. All human subjects' approvals were received, thus clearing the way to start the project.
- 2. Nine patients have been enrolled and eight completed the study. One dropped out due to her complicated medication regimen.
- 3. Patient satisfaction surveys have been administered to all patients enrolled in the study.
- 4. All clinic personnel have been trained and provided with username and passwords to follow their patients
- 5. Data collection has begun.

Advisory Board

- 1. The eleven member advisory board comprised of a diverse group of individuals is still in place;
- 2. Due to the delay in receiving human subjects' protection approval, the second follow up meeting of the advisory board has not been planned.

Reportable Outcomes:

- Presentations
 - Pam Angelus and Cherrel Christian presented a talk titled, "Interactive Web-based Technology: A Tool for Diabetes Management at the 32nd Annual American Association of Diabetes Educators in Washington DC on August 11, 2005.
- · Funding applied for based on work supported by this award

a. NIH STTR Phase I & Phase II fast track application: "Web-based tools for chronic disease management". Submitted July 2005, pending.

Conclusions:

This second year of the Medical Vanguard Diabetes Management Project continued to be a frustrating and educational year. The human subjects' requirements and subcontracting tasks continued to cost much time and money to get them in place. While we were able to better direct and assist the Native Communities in creating and submitting human subjects' applications, the time to get the protocols through was still longer than expected. The Medical Research and Material Command's review of new protocols from the Native Communities was much shorter due to the requests being submitted as a modification to the existing approved protocol.

A no-cost extension was granted which permits us time to recruit and enroll patients in the third year of the project while leaving enough time to complete an evaluation of the technology insertion.

The clinical personnel at each site continue to provide valuable feedback regarding the modification of MyCareTeam to fit their specific clinical needs. Personalized MyCareTeam sites were created this year for the Alaskan tribes and the Nez Perce Indians. Last year sites were created for the NNMC, MHA Nation, and the PBCI. These personalized sites allow the patients and providers affiliated with each site to feel more comfortable using the technology. We are still working on modifying MyCareTeam for the Hawaiian Native population.

Nine patients have been enrolled at the NNMC and some of the women have delivered their babies already. For those enrolled at NNMC, a satisfaction survey has been given them 2-4 weeks post enrollment and again around the time of delivery of their baby.

References:

- KE Smith, B Levine, SC Clement, MJ Hu, A Alaoui, SK Mun, "Impact of MyCareTeam for Poorly Controlled DM", Diabetes Technology and Therapeutics, 2004, Vol 6. Number 6, pp 828-835
- GT McMahon, HE Gomes, SH Hohne, TMJ Hu, BA Levine, PR Conlin, "Web-based Care Management in Patients with Poorly Controlled Diabetes Mellitus", Diabetes Care, 2005, Vol 28, 7, 1624-1629

Appendix A Patient Satisfaction Survey for National Naval Medical Center (NNMC) and For the Native Communities

Satisfaction with Telemedicine Survey (NNMC)

As part of your participation in the MyCareTeam Diabetes Management Project, I will ask you about your experiences in this program. Like your medical records, all of your responses are confidential and will not be shared with anyone outside of the program. Your honest answers are very important in helping us assess the quality of this medical program and we appreciate your participation.

The survey will take about ten (10) minutes. I will ask you about your experiences with MyCareTeam, your comfort with the online educational materials, and how you like communicating with your provider through MyCareTeam.

For most of the questions, I will read you a statement and ask whether you "strongly agree", "agree", are "neutral", "disagree", "strongly disagree", or "Not Applicable" with the statement.

Let's try one before we begin the formal survey. I will read you a statement and you can respond "strongly agree", "agree", "neutral", "disagree", "strongly disagree", or "Not Applicable".

Here is the statement: "I enjoy beautiful summer days".

[PROMPT FOR RESPONSE: Do you "strongly agree", "agree", are "neutral", "disagree", "strongly disagree", or "Not Applicable"]

Very good! Most of the survey will be asked in that fashion.

Before we begin, do you have any questions about the survey? If not, let's move on to the actual survey.

Satisfaction with Telemedicine Survey

INTERVIEWER READ: The following 6 statements concern your experiences with using the MyCareTeam Web site and technology. You should answer

"strongly agree", "agree", are "neutral", "disagree", "strongly disagree", or "Not Applicable" to each statement.

Us	e of Technology	5 ③	4	3 (2)	1	1 ③	na
1.	I find the MyCareTeam program easy to use.						
2.	The MyCareTeam Web pages display quickly.						
3.	MyCareTeam is available whenever I need it.						
4.	The links to other information are available when						
	I need them.	L					
5.	My current blood sugar readings are available on						
_	MyCareTeam whenever I check for them.	;					
6.	The graphics on MyCareTeam are friendly.						
7.	I am very comfortable using the computer and						
	the Internet in general.						
8.	In the time that I have used MyCareTeam, I have						
	asked for help with it from a friend or family						
	member.						

INTERVIEWER READ: The next five statements are about how you can learn about diabetes and caring for your disease through MyCareTeam. Remember to answer "strongly agree", "agree", are "neutral", "disagree, "strongly disagree",

or Not Applicable to each statement.

or Not Applicable to each statement.						
Method of Education	O	4	3 ⊕	2	1	na
9. I learn a lot from the MyCareTeam education						
pages.						
10. The information I seek is available on						
MyCareTeam or I am directed to the correct						
information.	ļ					
11. I have learned a lot about my disease from						
reviewing the analysis of my blood sugars on						
MyCareTeam.						
12. The information I find on MyCareTeam is						
presented clearly.						
13. The information I find on MyCareTeam is						
relevant to my situation.						

INTERVIEWER READ: The next five questions are about communicating with your care provider over MyCareTeam through messages or the comment section of the Data Summary Page. Remember to answer "strongly agree", "agree", are

"neutral", "disagree", "strongly disagree", or "Not Applicable" to each statement.

Method of Communication with Care Provider	5 ③	4	3 (£)	2	1	na
14. I communicate with my provider using						
MyCareTeam frequently.						
15. I find it easy to discuss issues with my care						
provider using MyCareTeam.						
16. I like communicating with my care provider over						
MyCareTeam.					L	
17. I communicate with my care provider about						
diabetes related issues using MyCareTeam.						

INTERVIEWER READ: We are nearly done with the survey. Now I am going to ask you two questions about features of MyCareTeam that do not have "coded" answers like the ones we just finished. Instead, you may answer these questions by selecting the features you use most often. You may select more than one feature for each question. The first question is directly related to the presentation of your blood sugar readings and the second about general features of MyCareTeam.

18. Please sele most often.	ct the MyCareTeam <u>blood sugar</u> display features that you use
	Blood Sugar Log Book
	Line Graph
	Time of Day Dependent Pie Charts
	Data Summary with Comments
19. Please sele	ct the MyCareTeam features that you use most often.
	Lab and Test Results
	Blood Sugar Log Book and Graphs
	Medications

	Exercise Log
	Data Summary with Comments
	Messaging
INTERVIE	WER READ: Lastly, now I am going to ask you three questions ackground and your access to computer and Internet technology.
	cheround and your access to computer and internet technology.
Background: 20. Please se	elect the highest level of education that you have:
	Some High School
	High School Degree (Diploma or GED Certificate)
	Some College
	Associate or Junior College Degree
	Bachelor's Degree
	Some Graduate School
	Graduate Degree
	Other (Interviewer prompt for response)
My	I am now going to read you five choices of places where you can use CareTeam. Il me the location you use most often:
	Home
	Work
	School
	Friend's or Family Member's home

 Community location like library, clinic, community center, etc
 I have never used MyCareTeam
ect all activities for which you use a computer or the Internet CareTeam:
 eMail
 Online shopping
 Online banking
 Play games on computer or Internet
 Instant messaging
Word processing
 Spreadsheets
 Work related tasks
 School work
 Find health information
Other

Satisfaction with Telemedicine Survey (Native Communities)

As part of your participation in the MyCareTeam Diabetes Management Project, I will ask you about your experiences in this program. Like your medical records, all of your responses are confidential and will not be shared with anyone outside of the program. Your honest answers are very important in helping us assess the quality of this medical program and we appreciate your participation.

The survey will take about ten (10) minutes. I will ask you about your experiences with MyCareTeam, your comfort with the online educational materials, and how you like communicating with your provider through MyCareTeam.

For most of the questions, I will read you a statement and ask whether you "strongly disagree", "disagree", are "neutral", "agree", "strongly agree", or "Not Applicable" with the statement.

Let's try one before we begin the formal survey. I will read you a statement and you can respond "strongly disagree", "disagree", "neutral", "agree", "strongly agree", or "Not Applicable".

Here is the statement: "I enjoy beautiful summer days".

[PROMPT FOR RESPONSE: Do you "strongly disagree", "disagree", are "neutral", "agree", "strongly agree", or "Not Applicable"]

Very good! Most of the survey will be asked in that fashion.

Before we begin, do you have any questions about the survey? If not, let's move on to the actual survey.

INTERVIEWER READ: The following 6 statements concern your experiences with using the MyCareTeam Web site and technology. You should answer "strongly disagree", "disagree", are "neutral", "agree", "strongly agree", or "Not Applicable" to each statement.

Use of the computer program	8	2	3 (2)	4	5 ©	па
I find the MyCareTeam program easy to use.						
2. MyCareTeam Web pages appear quickly on my						
computer screen.						
3. I can open up MyCareTeam whenever I need it.						
4. The links to other information can be opened when						
I need them.	_		- 			
5. My current blood sugar readings are available on						
MyCareTeam whenever I check for them.						
6. The graphics (pictures) on MyCareTeam help make						
it easier to use the program.						
7. I am very comfortable using the computer and the			1			
Internet.			L			
8. In the time that I have used MyCareTeam, I have						
asked for help with it from a friend or family						
member.		<u> </u>				

INTERVIEWER READ: The next five statements are about how you can learn about diabetes and caring for your disease through MyCareTeam. Remember to answer "strongly disagree", "disagree", are "neutral", "agree, "strongly agree", or Not Applicable to each statement.

Learning Method	1	2	3	4	5 ©	na
9. I learn a lot from the MyCareTeam education						
pages. 10. What I want to learn is on MyCareTeam or the						
program sends me to the right pages. 11.I have learned a lot about my diabetes from looking						
at the messages about my blood sugar numbers on MyCareTeam.						
12. The information I find on MyCareTeam is written so I can understand it.						
13. The information I find on MyCareTeam fits in with my lifestyle and is up to date.						

INTERVIEWER READ: The next five questions are about communicating with your care provider over MyCareTeam through messages or the comment section of the Data Summary Page. Remember to answer "strongly disagree",

"disagree", are "neutral", "agree", "strongly agree", or "Not Applicable" to each statement.

Method of talking with care provider		2	3 ⊕	4	5 😊	ца
14.I talk with my care provider using MyCareTeam often.						
15.I find it easy to talk about things with my care provider using MyCareTeam.						
16.I like talking with my care provider over MyCareTeam.						
17.I talk with my care provider about diabetes related issues using MyCareTeam.						

INTERVIEWER READ: We are nearly done with the survey. Now I am going to ask you two questions about features of MyCareTeam that do not have "coded" answers like the ones we just finished. Instead, you may answer these questions by selecting the features you use most often. You may select more than one feature for each question. The first question is directly related to the presentation of your blood sugar readings and the second about general features of MyCareTeam.

18. Please place a check (☑) mark next to the MyCareTeam blood sugar chart style that you use most often.

 Log Book
Line Graph
Bar Graph
Pie Chart



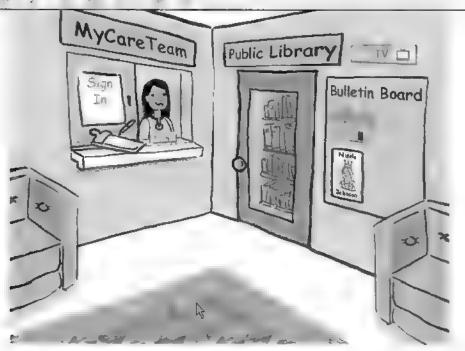
	Time of Day Pie Chart
19.Please place most often.	a check (☑) mark next to the MyCareTeam features that you use
	Lab Values
	Blood Sugar Logs
	Medications
	Exercise Log
***************************************	Data Summary
	Messaging
	Time Slot Dependent Pie Charts
INTERVIEW about your back	ER READ: Lastly, now I am going to ask you three questions kground and your access to computer and Internet technology.
Background: 20. Please select	the highest level of education that you have:
	Some High School
	High School Degree (Diploma or GED Certificate)
	Some College
	Associate or Junior College Degree
	Bachelor's Degree
	Some Graduate School

	Graduate Degree
	Other (Interviewer prompt for response)
	EWER: I am now going to read you five choices of places where you can use MyCareTeam. me the location you use most often:
	Home
	Work
	School
	Friend's or Family Member's home
	Community location like library, clinic, community center, etc.
	I have never used MyCareTeam
22. Please selection besides My	ct all activities for which you use a computer or the Internet CareTeam:
	eMail
	Online shopping
	Online banking
	Play games on computer or Internet
	Instant messaging
	Word processing
	Spreadsheets

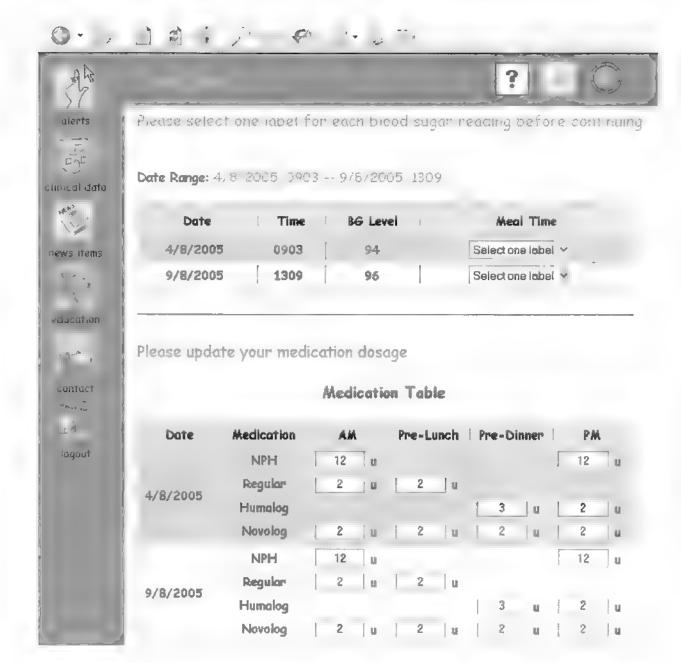
 Work related tasks
 School work
 Find health information
Other

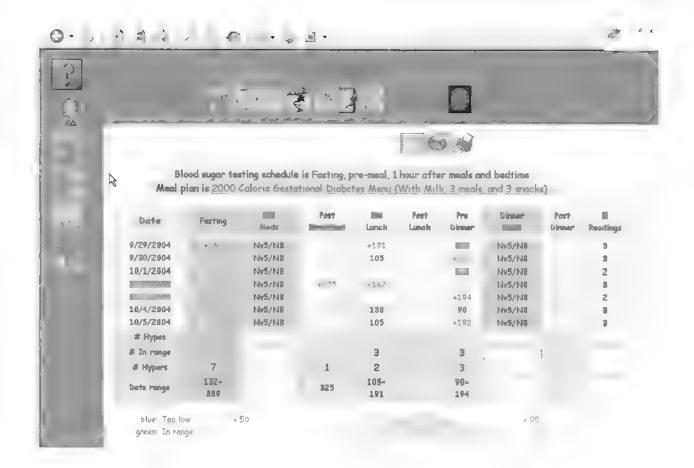
Appendix B MyCareTeam Screen Shots

Modified Lobby for Native Communities Blood Glucose Categorization for NNMC Blood Glucose Log Book for NNMC



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Appendix C Training Outline

MyCareTeam Training Schedule

- 1. Overview of Applications
 - a. Blood Glucose and Blood Pressure reading program
 - i. Retrieving data from the meters
 - ii. Entering a comment for the BG data
 - iii. Location of final data file
 - iv. Format of final data file
 - b. MCT Web Application
 - i. Patients side
 - ii. Practitioners side
 - iii. General Public Access
- 2. Blood Glucose and Blood Pressure reading program
 - a. Installation
 - b. Patient Use connections, running application
 - c. Creation of data file format and location
 - d. AccuLink and TeleCliniQ Devices
- 3. MyCareTeam Web Site
 - a. Connectivity How will patients connect to the Internet and therefore have access to MyCareTeam?
 - b. Logging in
 - c. Practitioner Use
 - i. Creation of new patients
 - ii. Entering lab values
 - iii. Use of reminders page
 - iv. Selecting patient's data to view from:
 - 1. Alert List
 - 2. New Data List
 - 3. All Patient List
 - v. Review of Patient Data
 - 1. Difference of selecting from Alert or New Data lists and all patients list
 - 2. Explanation of Patient Alert Page (Alert or New Data selection)
 - a. Alerts
 - b. Messages
 - c. Reminders
 - d. Clinical Data Icons
 - 3. Log Book Page
 - a. Categorization of received data
 - b. Date Range (default and how to change)
 - c. Graph options line, histogram, pie charts
 - d. Multiple readings for a time slot
 - e. Averages by TOD or Date
 - f. Overall average, range, Standard Deviation
 - g. Recognizing Hypo- & hyper- glycemic events & counts
 - 4. Lab Values
 - a. 12 month schedule
 - b. Message and clapping for HbA1C < 7

- c. Pop-up definitions
- 5. Medications
 - a. Ability to enter insulin, pump, and oral med prescriptions
 - b. Blood Pressure/Hypertension medications
 - c. Current and Previous prescriptions available
 - d. View other medications that the patient enters
- 6. Exercise Log
 - a. View current 14 day log
 - b. Change date range
- 7. Blood Pressure Log
 - a. View current 14 day log
 - b. Change date range
- 8. Summary Page
 - a. How it is created
 - b. Each field
 - c. Practitioner comments
 - d. Date range selectable
 - e. Graphing functions for current data view
 - f. Highlighted entry
- 9. Individual patient messaging
 - a. Messages order by date
 - b. Contain message sent to/from given patient by given user
 - c. Date selection from within messaging
 - d. New message preceded by red *
 - e. Viewing a message
 - f. Creating/Adding a message
 - g. Sending a message
 - h. Replying to a message
- vi. Checking for new messages All patient messaging
 - 1. Message Count
 - 2. Date selection from within messaging
 - 3. Viewing a message
 - 4. Creating a message
 - 5. Sending a message
 - 6. Replying to a message
- vii. Education Piece
 - 1. Georgetown educational material
- viii. Contacts
 - 1. View bios
 - 2. Send messages
 - 3. Emergency and general phone numbers
- d. Patient Use
 - i. Alerts and messages page
 - 1. Alerts
 - 2. Messages
 - 3. Reminders

- 4. Data Upload
- 5. News articles new and archive
- 6. Drill-down into hypo- and hyper- glycemic events
- 7. Enter comments
- 8. Pop-up definitions
- 9. Link to external web site (Need to identify what site this would be)

ii. Clinical Data

- 1. Log Book Page
 - a. Categorization of received data
 - b. Date Range (default and how to change)
 - c. Graph options line, histogram, pie charts
 - d. Multiple readings for a time slot
 - e. Averages by TOD or Date
 - f. Overall average, range, Standard Deviation
 - g. Recognizing Hypo- & hyper- glycemic events & counts

2. Lab Values

- a. 12 month schedule
- b. Message and clapping for HbA1C < 7
- c. Pop-up definitions

3. Medications

- a. View current and previous prescriptions available for insulin, oral meds, or pump prescription
- b. View current and previous blood pressure/hypertension medications
- c. Allow patient to enter other medications they may be taking

4. Exercise Log

- a. Enter new data into the exercise log
- b. View current 14 day log
- c. Change date range

5. Blood Pressure Log

- a. View current 14 day log
- b. Change date range

6. Summary Page

- a. Explain how it is created
- b. Each field
- c. Practitioner comments
- d. Entering comments (with data, from alert page, or here)
- e. Date range selectable
- f. Graphing functions for current data view

7. Individual patient messaging

- a. Messages order by date
- b. Messages sent to/from patient by all MCT members assigned to the patient
- c. Date selection from within messaging
- d. New message preceded by red *
- e. Viewing a message
- f. Creating/Adding a message

- g. Sending a message
- h. Replying to a message
- iii. Education
 - 1. Georgetown educational material
- iv. Contacts
 - 1. View bios
 - 2. Send messages
 - 3. Emergency and general phone numbers
- e. Logging out
 - i. Track usage log in and out times noted per user
 - ii. Return to lobby
 - iii. Access to education and news articles once the patient has logged out